



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusivity Under Non-exclusive Patent License: AAV Isolate and Fusion Protein Comprising Nerve Growth Factor Signal Peptide and Parathyroid Hormone**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Diabetes and Digestive and Kidney Disease and National Institute of Dental and Craniofacial Research, institutes of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an exclusive rights under active Non-exclusive Patent License to practice the inventions embodied in the United States, European and Japan Applications listed in the Supplementary Information section of this notice to Atsena Therapeutics, Inc., located in Durham, North Carolina, USA.

**DATES:** Only written comments and/or applications for a license which are received by the National Institute of Diabetes and Digestive and Kidney Disease's Technology Advancement Office on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Vladimir Knezevic, MD, (Senior) Advisor for Commercial Evaluation, Technology Advancement Office, Building 12A, Room 3011, Bethesda, MD 20817-5632 (for business mail), Telephone: (301)-435-5560; E-mail: [vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Intellectual Property**

- I. European Patent National Stage: EP3294894 granted 2019-08-14, entitled “*AAV isolate and fusion protein comprising nerve growth factor signal peptide and parathyroid hormone*” (HHS Reference Number E-175-2015-1-EP-03), validated in Great Britain, France and Germany.
- II. Japanese Application No. 2017-558710 granted 2020-12-20, entitled “*AAV isolate and fusion protein comprising nerve growth factor signal peptide and parathyroid hormone*” (HHS Reference Number E-175-2015-1-JP-04).
- III. U.S. Patent Application No. 15/573,214 filed 2017-11-10, entitled “*AAV isolate and fusion protein comprising nerve growth factor signal peptide and parathyroid hormone*” (HHS Reference Number E-175-2015-1-US-05).
- IV. Canadian Patent Application No. 2,985,786 filed 2017-11-10, entitled “*AAV isolate and fusion protein comprising nerve growth factor signal peptide and parathyroid hormone*” (HHS Reference Number E-175-2015-1-CA-02).

The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to treatment of limited number of monogenic inherited retinal diseases that affect the photoreceptors and/or retinal pigmented epithelium.

The above-listed patent portfolio covers inventions directed to gene therapy and specifically, expression vectors and therapeutic methods of using such vectors.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Diabetes and Digestive and Kidney Disease receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license

applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 22, 2021.

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